DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2015

Biodenta Swiss AG
Mr. David Elier
Regulatory Manager
Tramstrasse 16
CH-9442 Berneck
Switzerland

Re: K150296
Trade/Device Name: Biodenta Customized Abutment - Hybrid
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 28, 2015
Received: June 1, 2015

Dear Mr. Elier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150296

Device Name

Biodenta Customized Abutment - Hybrid

Indications for Use *(Describe)*

The Biodenta Customized Abutment - Hybrid is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

The Biodenta Customized Abutment - Hybrid is compatible with the following dental implant systems:

Implant Brand, Type	Implant Platform Name: Implant Diameter
Biodenta, Bone Level and Tapered	B1: 3.5 mm; B2: 4.1, 4.8, 6.0 mm
Nobel Biocare, Nobel Replace straight and tapered	NP: 3.5 mm; RP: 4.3 mm; WP: 5.0 mm; 6.0: 6.0 mm
Nobel Biocare, NobelActive	NP: 3.5 mm; RP: 4.3, 5.0 mm
Biomet 3i, Certain Internal	3.4: 3.25, 4.0 mm; 4.1: 4.0, 5.0 mm; 5.0: 5.0, 6.0 mm; 6.0: 6.0 mm
Dentsply, Astra Tech OsseoSpeed	3.5/4.0: 3.5, 4.0 mm; 4.5/5.0: 4.5, 5.0 mm
Straumann, Bone Level	NC: 3.3 mm; RC: 4.1, 4.8 mm
Zimmer, Screw Vent and Screw Vent Tapered	3.5: 3.3, 3.7, 4.1 mm; 4.5: 4.7 mm; 5.7: 6.0 mm

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K150296

510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
Fax number:	+ 41 71 747 11 12
Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	January 30, 2015

Trade / proprietary name:	Biodenta Customized Abutment - Hybrid
Common name:	Endosseous dental implant abutment
Device classification name:	Endosseous Dental Implant Abutment
Product code:	NHA
Regulation number :	21 CFR 872.3630
Device class:	II

Legally marketed device to which equivalence is claimed (predicate device):

1. Company:	Pou Yu Biotechnology Co., Ltd.
Device name:	TDS Abutment for Nobel Biocare Replace
510(k) number:	K091026 – Reference Predicate
2. Company:	Pou Yu Biotechnology Co., Ltd
Device name:	TDS Abutment for Friadent Xive,
510(k) number:	K103339 - Primary Predicate

3. Company:	Straumann USA, LILO
Device name:	Straumann® Variobase™ Abutments
510(k) number:	K132219 – Reference Predicate
4. Company:	Biodenta Swiss Ag
Device name:	Biodenta Dental Implant System - Multi-Use Abutment
510(k) number:	K123491 – Reference Predicate
5. Company:	Biodenta Swiss Ag
Device name:	Biodenta Customized Abutment
510(k) number:	K110778 – Reference Predicate

Indications for Use:

The Biodenta Customized Abutment - Hybrid is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

The Biodenta Customized Abutment - Hybrid is compatible with the following dental implant systems:

Implant Brand, Type	Implant Platform Name: Implant Diameter
Biodenta, Bone Level and Tapered	B1: 3.5 mm; B2: 4.1, 4.8, 6.0 mm
Nobel Biocare, Nobel Replace straight and tapered	NP: 3.5 mm; RP: 4.3 mm; WP: 5.0 mm; 6.0: 6.0 mm
Nobel Biocare, NobelActive	NP: 3.5 mm; RP: 4.3, 5.0 mm
Biomet 3i, Certain Internal	3.4: 3.25, 4.0 mm; 4.1: 4.0, 5.0 mm; 5.0: 5.0, 6.0 mm; 6.0: 6.0 mm
Dentsply, Astra Tech OsseoSpeed	3.5/4.0: 3.5, 4.0 mm; 4.5/5.0: 4.5, 5.0 mm
Straumann, Bone Level	NC: 3.3 mm; RC: 4.1, 4.8 mm
Zimmer, Screw Vent and Screw Vent Tapered	3.5: 3.3, 3.7, 4.1 mm; 4.5: 4.7 mm; 5.7: 6.0 mm

Device Description:

The Biodenta Customized Abutment - Hybrid is a two-piece abutment, which contains a pre-manufactured (stock) Titanium-Base and a Zirconium coping and/or crown that is designed by a dental technician using CAD software and manufactured at Biodenta milling centers.

The Biodenta Customized Abutment - Hybrid utilizes an Abutment Screw for abutment retention. The final cement retained restoration is constructed in the lab according to the dentist's specifications.

The Biodenta Customized Abutment - Hybrid is compatible with the following dental implant systems: Biomet 3i, Certain Internal; Dentsply, AstraTech OsseoSpeed; Zimmer, Screw Vent; Nobel Biocare, NobelActive; Nobel Biocare, NobelReplace; Straumann, Bone Level; Biodenta, Bone Level and Tapered

The Titanium-Base and the Abutment Screw of the Biodenta Customized Abutment - Hybrid are made of biocompatible Ti-6Al-4V ELI conforming to ISO 3852-3 and ASTM F136.

The Zirconium coping and/or crown of the Biodenta Customized Abutment - Hybrid are made of biocompatible ZrO_2 conforming to ISO 13356 Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).

Non-clinical Testing Data:

Fatigue testing was conducted according to FDA Guide: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff. The worst case scenario for the Biodenta Customized Abutment - Hybrid and implant was tested. The results show that the Biodenta Customized Abutment - Hybrid has sufficient mechanical strength for the intended clinical application.

The compatibility of the Biodenta Customized Abutment - Hybrid compatible to the implants Biomet 3i, Certain Internal; Dentsply, AstraTech OsseoSpeed; Zimmer, Screw Vent; Nobel Biocare, NobelActive; Nobel Biocare, NobelReplace; and Straumann, Bone Level implants has been verified by and Engineering and Compatibility analysis

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Customized Abutment - Hybrid is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

Summary Substantial Equivalence Comparison to predicate devices:

	Subject Device	Predicate Devices				
Company	Biodenta Swiss AG	Pou Yu Biotechnology Co., Ltd.	Pou Yu Biotechnology Co., Ltd.	Straumann USA, LILO	Biodenta Swiss Ag	Biodenta Swiss AG
Device Name	Biodenta Customized Abutment - Hybrid	TDS Abutment for Nobel Biocare Replace	TDS Abutment for Friadent Xive,	Straumann® Variobase™ Abutments	Biodenta Dental Implant System - Multi-Use Abutment	Biodenta Customized Abutment
510(k) Number	New device	K091026	K103339	K132219	K123491	K110778
Intended use	The Biodenta Customized Abutment - Hybrid is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. The Biodenta Customized Abutment - Hybrid is compatible with the following dental implant systems: -Biodenta, Bone Level and Tapered B1: 3.5 mm; B2: 4.1, 4.8, 6.0 mm -Nobel Biocare, Nobel Replace straight and tapered NP: 3.5 mm; RP: 4.3 mm; WP: 5.0 mm; 6.0: 6.0 mm -Nobel Biocare, NobelActive NP: 3.5 mm; RP: 4.3, 5.0 mm -Biomet 3i, Certain Internal 3.4: 3.25, 4.0 mm; 4.1: 4.0, 5.0 mm; 5.0: 5.0, 6.0 mm; 6.0: 6.0 mm -Dentsply, Astra Tech OsseoSpeed 3.5/4.0: 3.5, 4.0 mm; 4.5/5.0: 4.5, 5.0 mm -Straumann, Bone Level NC: 3.3 mm; RC: 4.1, 4.8 mm -Zimmer, Screw Vent and Screw Vent Tapered 3.5: 3.3, 3.7, 4.1 mm; 4.5: 4.7 mm; 5.7: 6.0 mm	TDS Abutment for Nobel Biocare Replace is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.	TDS Abutment for Friadent Xive is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. This device is compatible with the following implant systems which have an internal hex with flat-to-flat dimensions of 1.78mm or greater: Firadent: FRIALIT Implant, XiVA Implant; 3i: Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; Biohorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System, Laser-lok® 3.0 implant system; Lifecore: Lifecore RENOVA™ Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; Osstem: GS System; Nobel Biocare: Active Implant.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straiumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	Biodenta Dental Implant System Multi Use Abutments are intended for terminal or intermediate abutment support for fixed or removable crown, bridgework and to retain overdentures.	The Biodenta Customized Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. The Biodenta Customized Abutment is compatible with the following implant systems: - Internal hex systems with flat-to-flat dimensions of 1.78mm or greater: Firadent: FRIALIT Implant, XiVA Implant; 3i: Certain Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; BioHorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System; Lifecore: Lifecore RENOVA™ Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System.- Nobel Biocare Replace: NobelReplace Straight, NobelReplace Tapered; Replace Select Tapered, Replace Select Straight; for the NP, RP, WP and 6.0 implants.- External hex systems with flat-to-flat dimensions of 2.4mm or greater: Nobel Biocare Branemark, 3i, BioHorizons, and Lifecore.

Compatible implant types	- Biomet 3i, Certain Internal - Dentsply, AstraTech OsseoSpeed - Zimmer, Screw Vent - Nobel Biocare, NobelActive - Nobel Biocare, NobelReplace - Straumann, Bone Level - Biodenta, Bone Level and Tapered	- Nobel Biocare, NobelReplace	- Biomet 3i, Certain Internal - Dentsply, AstraTech OsseoSpeed - Zimmer, Screw Vent - Nobel Biocare, NobelActive	- Straumann, Bone Level	- Biodenta, Bone Level and Tapered	- Biomet 3i, Certain Internal - Dentsply, AstraTech OsseoSpeed - Zimmer, Screw Vent
Custom Design						
Abutment Angulation	0 - 30º	0 - 30º	0 - 30º	0 - 30º	0, 18, 30º	0 - 30º
Abutment Diameter	4.5 - 15 mm	5 - 10 mm	5 - 10 mm	3.8 - 7.0 mm	4.5 - 5.0 mm	5 - 10 mm
Zr Crown/ Coping Height	5.0 - 10 mm	3.0 - 7.5 mm	3.0 - 7.5 mm	unknown	Not Applicable (one-piece stock Ti abutment)	Not Applicable (one-piece customized Ti abutment)
Final Abutment Height	5.5 - 12.3 mm	3.5 - 8.0 mm	3.5 - 8.0 mm	3.5 mm - unknown	2.0 - 5.5 mm	3.0 - 7.5 mm
Abutment fixation	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw
2 Piece	2 piece: - pre-manufactured (stock) titanium-Base and -CAD/CAM Zirconium coping/crown	2 piece: - pre-manufactured (stock) titanium-Base and -CAD/CAM Zirconium coping/crown	2 piece: - pre-manufactured (stock) titanium-Base and -CAD/CAM Zirconium coping/crown	2 piece: - pre-manufactured (stock) titanium-Base and -CAD/CAM Zirconium coping/crown	1 piece: - pre-manufactured (stock) titanium abutment	1 piece: - titanium CAD/CAM abutment
CAD/CAM Processing	Yes – Zirconium part milled in Biodenta milling center under QSR control	Yes – Zirconium part milled in manufacturers milling center under QSR control	Yes – Zirconium part milled in manufacturers milling center under QSR control	Yes – Zirconium part milled in Straumann milling center under QSR control	No	YES - Titanium abutment milled in Biodenta Milling Center under QSR control
Material						
Metal Base	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-7Nb	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Coping	ZrO2	ZrO2	ZrO2	ZrO2	Not applicable	Not applicable
Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-7Nb	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Mechanical						
Mechanical Testing	Completed Fatigue Testing according to ISO 14801:2007	Completed Fatigue Testing according to ISO 14801:2007	Completed Fatigue Testing according to ISO 14801:2007	Completed Fatigue Testing according to ISO 14801:2007	Completed Fatigue Testing according to ISO 14801:2007	Completed Fatigue Testing according to ISO 14801:2007
Sterile / Reuse						
Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile
Reusable	no	no	no	no	no	no